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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO		
09/758,917	01/11/2001	Ashok Tehim	T8466360US3	9294		
7	590 07/28/2003					
Carolyn S. Elmore			EXAM	EXAMINER		
HAMILTON, I Two Militia Dr	BROOK, SMITH & ŘEY ive	HUANG, EVELYN MEI				
Lexington, MA	02421-4799	ART UNIT	PAPER NUMBER			
		1625				
			DATE MAILED: 07/28/2003	14		

Please find below and/or attached an Office communication concerning this application or proceeding.

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			Application No.		Applicant(s)			
	Off:	A - 45 C	09/758,91	7	TEHIM ET AL.			
	Onic	Action Summary	Examiner		Art Unit			
	TL - 154	INO DATE of this communication on	Evelyn Hu		1625	14		
Period fo		ING DATE of this communication ap	pears on the	cover sneet with the c	orrespondence ad	iaress		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the accommendation of SU.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  - Status								
1)⊠	Respons	ive to communication(s) filed on 27	May 2003 .					
2a)	This action	on is <b>FINAL</b> . 2b)⊠ T	his action is	non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims								
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4) \( \sum \) Claim(s) \( \frac{1-7 \text{ and 9-19}}{1-7 \text{ signs pending in the application.}} \)								
4a) Of the above claim(s) <u>14-19</u> is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.								
6) Claim(s) 1-6 and 9-13 is/are rejected.								
7)⊠ Claim(s) <u>Z</u> is/are objected to.								
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers								
9) The specification is objected to by the Examiner.								
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12) ☐ The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. §§ 119 and 120								
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) ☐ All b) ☐ Some * c) ☒ None of:								
	1.⊠ Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>								
Attachmen	it(s)							
2) D Notic	e of Draftsper	es Cited (PTO-892) son's Patent Drawing Review (PTO-948) sure Statement(s) (PTO-1449) Paper No(s)			(PTO-413) Paper No Patent Application (PT			
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Art Unit: 1625

#### DETAILED ACTION

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-27-2003 has been entered.

#### Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in United Kingdom on 5-27-1997 and 10/21/1996. It is noted, however, that applicant has not filed a certified copy of the foreign applications as required by 35 U.S.C. 119(b).

#### Election/Restrictions

3. Claims 1-7, 9-19 are pending. Claim 8 has been canceled according to the amendment filed on 7-12-2002. Claims 14-19 are withdrawn from further consideration as being drawn to the non-elected invention.

Applicant requests that claims 14-19 be considered as they are drawn to a single inventive concept. On the contrary, the application contains claims to more than one of the combination of categories of invention since it contains 6 different alternative processes of use. The restriction as indicated is therefore improper.

Art Unit: 1625

### Claim Rejections - 35 USC § 102

4. The 35 U.S.C. 102(b) rejection over Costi is withdrawn because the deletion of the prior art compound of Costi has set a demarcation from the prior art.

#### **Double Patenting**

The provisionally obviousness-type double patenting over the corresponding claims of copending Application No. 09/457606 is now obviousness-type double patenting over US Patent No. 6492380. Applicant maintains that the present amendment has set a demarcation from the allowed claims of the patent. The method claims in the patent are species within the instant generic method claim, wherein R1 is loweralkyl carbonate (a definition of which is not found the specification, but compound of R1 being acetic acid is described as preferred embodiment on page 9 of the specification).

## Claim Rejections - 35 USC § 103

- 6. The 103(a) rejection over Brana (4204063) is withdrawn since the compound, 1,3-dioxo-5-nitro-N-propylmorpholino-1,2,3,4-tetrahydrobenzo[I]-isoquinoline, has been deleted from the amended claim 5, thereby setting a demarcation from Brana. Motivation to modify the prior art compound to arrive at the instant is lacking.
- 7. The 103(a) rejection over Sestanj I (3821383, PTO-1449) is withdrawn since the ethyl ester of 5-nitro- 1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid has been excluded from the amended claim 5, thereby setting a demarcation from Brana. Motivation to modify the prior art compound to arrive at the instant is lacking.
- 8. The rejection for Claims 1-6, 9-12 under 35 U.S.C. 103(a) as being unpatentable over Sestanj I (3821383, PTO-1449) in view of Malizia (EP 206322, PTO-1449) is withdrawn for claims 5, 6 in view of the deletion of the obvious compounds from the claims, but it is

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Art Unit: 1625

maintained for amended claims 1-4, 9-12 because the compound in the amended claims wherein R1 is loweralkyl carbonate still encompasses the prior art compound wherein R1 is acetic or propionic acid, which is obvious over the instant. While the definition of loweralkyl carbonate is not found in the specification, compound of R1 being acetic acid is described as preferred embodiment on page 9 of the specification.

9. The rejection for Claim 13 under 35 U.S.C. 103(a) as being unpatentable over Sestanj I (3821383, PTO-1449) in view of Malizia (EP 206322, PTO-1449) and further in view of Bundgaard is withdrawn in view of the deletion of 3-nitro-1,8-(N-propioncarboxylate) succinamidonapthalene from the amended claim 13. Motivation to modify the prior art compound to arrive at the instant is lacking.

#### Claim Rejections - 35 USC § 112

10. The rejection for Claims 5, 6 under 35 U.S.C. 112, second paragraph, set forth in the final rejection is withdrawn in view of the deletion of 2-{2-(4-methylphenyl-sulphon-amido)-5,5-dichlorophenyl}-naphthalimide (wherein R2 and R3 are both hydrogen), 1,3-dioxo-5-nitro-N-propyl*morpholino*-1,2,3,4-tetrahydrobenzo[I]isoquinoline, *5-amino*-N-butylnaphthalimide from claim 5 and the deletion of 2-{2-(4-methylphenyl-sulphonamido)-5,5-dichlorophenyl}-naphthalimide (wherein R2 and R3 are both hydrogen) from claim 6.

## Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-4, 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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Art Unit: 1625

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The compound in proviso (ii), i.e. the compound wherein when R3 is nitro, R1 is benzyl is not described in the specification. The rejection is applicable to claims dependent on claim 1.

## Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 5, 13, for the compound, 3-amino-7,4-bis(ethyl-1,3-dioxo)-1,2,34-terahydrobenzo[i]isoquinoline, it is unclear whether the 'bis' refer to the 1,2,3, 4-terahydrobenzo-[i]isoquinoline or not. If it were the case, how are they linked? Please provide a structure for this compound in the next response to facilitate the examination process.
- b. Some of the compounds, such as the 4<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup> compound of the amended claim 5 and the 3<sup>rd</sup> compound of the amended claim 6, have no antecedent basis in the base claims 1 and 2 respectively. Please provide structures for these compounds in the next response to facilitate the examination process.
- c. Claim 6, the closing parenthesis is missing in the 3<sup>rd</sup> compound. The structure of this compound is unclear to the examiner.

#### Allowable Subject Matter

13. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1625

The composition comprising a compound wherein R1 is aminoethanol as recited in the instant claim is not taught or suggested by all of the prior art of record.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Evelyn Huang Primary Examiner

Art Unit 1625

July 14, 2003